

Remarks:

Claims 1 to 35 remain in the application. Claims 1 to 12 and 26 to 35 are subject to examination and claims 13 to 25 have been withdrawn from examination. Claims 1, 2, 9, 12, and 33 have been amended. Claim 6 has been cancelled.

Reconsideration of the application is requested.

(Page 2) Rejection under 35 U.S.C. § 112

In items 3 to 6 on page 2 of the above-identified Office action, claim 12 is rejected under 35 U.S.C. § 112, second paragraph. Specifically, the Examiner states: "since a 'folded tissue' cannot be 'separate pieces of tissue', the claim is rendered vague and indefinite."

Accordingly, claim 12 has been amended to no longer depend from claim 1. Amended claim 12 now depends from amended claim 33. It is therefore believed that the Examiner's rejection has been overcome and that claim 12 is allowable. Such allowance is hereby requested.

(Page 5) Allowable Subject Matter

The Applicants wish to thank Examiner Erez for indicating the allowable subject matter of claims 2 to 5. Upon review of the syntax of claim 2 and considering Examiner Erez's likely motivation for allowing claims 2 to 5 (while continuing to reject claim 1), Applicants realized that the language of claim 1 could have even more clearly recited the features of the invention being claimed. Applicants believe that Examiner Erez's interpretation of what was being claimed was not consistent with the features of the present invention. As such, claims 1 and 2 have been clarified to indicate that the body tissue in the last two paragraphs of the body is the same body tissue as recited in the first paragraph of the body. As so clarified, claim 1 reads, in part, as follows:

manipulating body tissue so that said tissue is folded on itself...

subsequently advancing a clip over said folded body tissue...

subsequently bending said piercing portion of at least one of said two arms through more than one half a thickness of said folded body tissue...

It is now clear from the language of amended claim 1 that the piercing portion is passing at least past the midpoint of the folded tissue and not just into one of two layers of the fold.

It is Applicants' belief that the Examiner considered original claim 2 allowable because of an understanding that claim 2 required the piercing to occur past the midway point of the folded tissue. Now that claim 1 has been clarified to show that this feature was *originally present* in claim 1, it is believed that claim 1 is allowable. It is further believed that claim 2 is still allowable because the prior art does not show or suggest "bending said piercing portion **completely through** said folded body tissue," i.e., through both of the two thicknesses of the folded body tissue. (Emphasis added by applicants.)

Claim 2 has been amended to be consistent with claim 1 and solely for the purposes of clarifying the features. Both the amendments to claims 1 and 2 were made independent of reasons of patentability and do not narrow the scope of the claims. Accordingly, the claim amendments do not limit the range of any permissible equivalents.

Claims 3 to 5 ultimately depend from claim 1, which is now believed to be allowable. Claims 3-5 are now allowable as well, and the Examiner's rejection should be withdrawn.

Claims 27, 28, 31, 32, 34 and 35 have been indicated as allowable. Thus, allowance of claims 27, 28, 31, 32, 34 and 35 is hereby respectfully requested as well.

(Page 2) Rejection under 35 U.S.C. § 103(a)

In items 7 to 10 on page 3 of the above-identified Office action, claims 1, 7 to 12, 26, 29, 30, and 33 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,434,796 to Karapetian et al. (hereinafter "Karapetian") in view of U.S. Patent No. 5,403,326 to Harrison et al. (hereinafter "Harrison").

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Amended independent claim 1 reads, in part, as follows:

manipulating body tissue so that said tissue is folded on itself...

subsequently advancing a clip over said folded body tissue...

subsequently bending said piercing portion of at least one of said two arms through more than one half a thickness of said folded body tissue...

Independent claim 29 recites:

advancing a clip over body tissue folded on itself...

Amended independent claim 33 recites:

advancing a clip over outside surfaces of two thicknesses of body tissue disposed substantially parallel to one another.

The present invention provides a device that applies a clip to a folded tissue, e.g., a tented portion of a fundus. As shown in FIG. 10 of the instant application, the folded tissue is grasped and pulled in between the open jaws of the clip applier. See, e.g., pages 19 to 20 of the specification of the instant application. The jaws of the clip applier are then closed onto the folded tissue as shown in FIG. 11. *Id.* When the jaws are completely closed (or closed as much as possible), they are preferably locked, the grasper is optionally released, and the clip pusher is activated to push forward a clip 106 as shown in FIG. 12. *Id.* After the clip 106 is applied, the jaws of the clip applier are opened as shown in FIG. 13 and the clip 106 remains in place to plicate the folded tissue (e.g., fundus). *Id.*

Karapetian recites a surgical staple device that secures two adjacent pieces of **bone** in a fixed orientation to allow pieces of bone to heal. See Karapetian at col. 2, lines 40 to 51. The Examiner admits that “Karapetian discloses two layers formed from **separate** tissues;” in other words, in no way can Karapetian be used to disclose or suggest a process that requires “folded body tissue” (claim 1) or “body tissue folded on itself” (claim 29). The Examiner accurately recognizes and admits on page 4 of the Office action that Karapetian does not disclose the step of “manipulating the tissue to form a fold” -- this is, of course, because bone cannot be folded!

The Examiner then combines Harrison for the purpose of showing “a method of attaching folded tissue together”. Office action at page 4, third paragraph. If Karapetian discloses a process where tissue is never envisioned to be folded and, in fact, teaches nothing with regard to folding tissue, then it is inappropriate to say that a reference disclosing the mere folding of tissue would be or could be combined by one skilled in the art with the disclosure of Karapetian. This is not only an issue of the references teaching away from the claimed invention, but this rejection creates a situation where the two allegedly combinable references actually teach away from one another!

Applicants respectfully disagree with the Examiner’s conclusion that Karapetian discloses layers or can be combined with Harrison to arrive at the invention of the instant application. The present invention is used on soft tissue, which, unlike bone, can be “folded.” Karapetian discloses a surgical staple that is **only used on bone and cannot be used on “soft” tissue**. Karapetian is very clear on this principle difference and discloses: “one of the rods 3 is made to penetrate bone fragments, whereas the other rod is driven into the other bone fragment.” Karapetian at col. 2, lines 40 to 45. Perhaps the clearest statement in the text of Karapetian of the impossibility of using the disclosed surgical staple in soft tissue is the following:

a force is applied to the staple web 2. As a result the staple is acted upon by said force to move toward the rods, the staple legs 1 thrust against the rounded-off portion 10 to get bent and to penetrate into the bone tissue, thus strongly uniting the bone fragments...”

Id. at lines 46 to 50. This metal-bending force could not be applied if the rods were in soft tissue, as the force would simply distort and most likely damage the soft tissue instead of bending metal. Even further evidence of Karapetian’s bone-only use is shown by the removal process of FIGS. 3 and 4 therein, where the legs are extracted with a force that, again, bends the metal legs, while the rods remain fixedly inserted in the bone. Because the surgical staple of Karapetian would not work with and would only damage soft tissue, Karapetian completely *teaches away from* using the surgical staple in soft tissue. **Prior art that teaches away is per se demonstration of lack of prima facie obviousness.**¹ Karapetian clearly teaches away from

¹ The Supreme Court holds that “when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (U.S. 2007).

folding tissue and claims 1 and 29 require this. As such, Karapetian cannot be said to suggest the features of the claims in any way.

The above equally applies to independent claim 33. Additionally, claim 33 provides that the clip is advanced “over . . . outside surfaces of said body tissue.” Nowhere in Karapetian is this feature disclosed and, in fact, it cannot even be contemplated. In every embodiment of Karapetian, the staple pierces the outside surfaces -- it does not advance over those surfaces. Moreover, claim 33 provides that the two thicknesses are parallel to one another” such that the “two opposing outside surfaces [are] substantially parallel” to the intermediate plane of the two tissue thicknesses and, therefore, substantially parallel to one another. Each of the figures of Karapetian illustrate the surgical staple spanning a crack (i.e., the intermediate plane) to couple two pieces of bone that are disposed adjacent to one another.

The Supreme Court has held that the Federal Circuit’s teaching, suggestion, or motivation test is not inconsistent with the analysis set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), and can be used in the “expansive and flexible approach” of determining obviousness *vel non*. *KSR*, 127 S. Ct. at 1739. See also *DyStar Textilfarben GmbH & Co. Deutschland KG. v C.H. Patrick Co.*, 464 F. 3d 1356, 1367 (Fed. Cir. 2006) (flexible approach); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1291 (Fed. Cir. 2006) (flexibility in obviousness jurisprudence). Applied to the circumstances here, there is no teaching, no suggestion, and no motivation to arrive at the features of the instant claims.

It is well settled that almost all claimed inventions are but novel combinations of old features. The courts have held in this context, however, that when “it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation **in the prior art** to make the selection made by the applicant”. *Interconnect Planning Corp. v. Feil*, 227 USPQ 543, 551 (Fed. Cir. 1985) (emphasis added). “Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination”. *In re Bond*, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). “Under Section 103 teachings of references can be combined **only** if there is some suggestion or incentive to do so.” *ACS*

Hospital Systems, Inc. v. Montefiore Hospital et al., 221 USPQ 929, 933, 732 F.2d 1572 (Fed. Cir. 1984) (emphasis original). “Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be ‘**clear and particular.**’” *Winner Int’l Royalty Corp. v. Wang*, 53 USPQ2d 1580, 1587, 202 F.3d 1340 (Fed. Cir. 2000) (emphasis added; citations omitted); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 56 USPQ2d 1456, 1459 (Fed. Cir. Oct. 17, 2000). Appellant respectfully believes that there is no “clear and particular” teaching or suggestion in Karapetian to incorporate the features of Harrison, and there is no “clear and particular” teaching or suggestion in Harrison to incorporate the features of Karapetian.

In establishing a *prima facie* case of obviousness, **it is incumbent upon the Examiner** to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion, or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the appellant’s disclosure. See, for example, *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir. 1988), *cert. den.*, 488 U.S. 825 (1988). The Examiner has not provided the requisite reason why one of ordinary skill in the art would have been led to modify Karapetian with Harrison or to combine Karapetian’s teachings with Harrison’s teachings to arrive at the claimed invention.

Applicants respectfully believe that the burden for satisfying the above requirements has not been met to allow a combination rejection to stand.

For the foregoing reasons, independent claims 1, 29, and 33, as amended, distinguish over Karapetian et al. taken alone and/or in view of Harrison et al. Claims 7-12, and 26 depend from claim 1 and claim 30 depends from independent claim 29. Since dependent claims contain all the limitations of the independent claims, claims 7-12, and 26 distinguish over Karapetian et al.

taken alone and/or in view of Harrison et al. as well, and the Examiner's rejection should be withdrawn.

In view of the foregoing, reconsideration and allowance of claims 1 to 12 and 26 to 35 are solicited.

In the event the Examiner should still find any of the claims to be unpatentable, counsel would appreciate receiving a telephone call so that, if possible, patentable language can be worked out.

If an extension of time for this paper is required, petition for extension is herewith made.

The extension fee for response within a period of one (1) month pursuant to Section 1.136(a) in the amount of \$120.00 in accordance with Section 1.17 is enclosed herewith.

Respectfully submitted,

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